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David T. Read
Acting Director Health Assessment Policy Staff, CDER
Food and Drug Administration
1451 Rockville Pike, HFD-7
Rockville, MD 20852

Dear Mr. Read:

Transmitted herewith is a copy of the application for patent term extension (PTE) of U.S. Patent No. 5,776,944. The application was filed on May 29, 2003, under 35 U.S.C. § 156. Concurrent with the filing of the PTE application in the subject patent, the same applicant filed applications for PTE identifying the same product (FACTIVE®) in U.S. Patent Nos. 5,633,262 and 5,962,468.

The patent claims a product and a process for the preparation thereof that was subject to regulatory review under the Federal Food, Drug and Cosmetic Act. Subject to final review, the subject patent is considered to be eligible for patent term restoration. Thus, a determination by your office of the applicable regulatory review period is necessary. Accordingly, notice and a copy of the application are provided pursuant to 35 U.S.C. § 156(d)(2)(A).

Inquiries regarding this communication should be directed to the undersigned at (703) 306-3159 (telephone) or (703)872-9411 (facsimile).

Karin Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Charles E. Van Horn
Finnegan, Henderson, Farabow, Garrett & Dunner. L.L.P.
1300 I Street, N.W.
Washington, D.C. 20005-3315

RE: FACTIVE® (gemifloxacin mesylate)
Docket No. 9009.0008